

REMARKS

This Amendment and Response is submitted in response to the Final Office Action mailed 13 JANUARY 2003. The response is accompanied by a Request for Continued Examination (RCE), and the requisite fee. Withdrawal of the rejection and reconsideration with an eye toward allowance is respectfully requested. Applicants appreciate the Examiner's willingness to discuss the Application and rejections in the 31 March 2003 interview.

Claims 36-39, 45-47, 49, 50, and 52-53 are pending. Claims 36-39, 45-47, and 49-52 stand rejected. Claims 36 and 50 are amended herein. The claim amendments are presented in a revised format per the USPTO's announcement 'Amendments in a Revised Format Now Permitted', signed 31 January 2002, and accordingly do not conform to the current reading of 37 C.F.R. §1.121, which Applicants understand has been waived. Accordingly, a complete listing of all claims that are, or were in the application, along with an appropriate status identifier, is provided above in the section entitled "Amendments to the Claims". Markings are provided on claims amended in the present amendment.

Support for the above claim amendments can be found throughout the specification, figures, and originally filed claims. For example, support for the amendment to claim 52 can be found at least in FIG. 1A.

Drawings

Applicants note with appreciation that the proposed drawing corrections and substitute sheets of drawings, filed on 30 October 2002 were approved. Two (2) sheets of formal drawings are attached, representing figures 1A-D and 2. Applicants submit that the drawings are now in condition for allowance.

Claim Rejections – 35 U.S.C. §112

Claims 36-39, 35-37, 49, 50, and 52-53 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicants again thank Examiner Starsiak and Examiner Nguyen for the useful discussion during the interview. As discussed then, the claims appeared to meet the requirements of §112 based on the following arguments.

The Examiner rejected claims 36-39, 45-49, 50, 52, and 53 as incomplete. In particular, the Examiner suggested that the elements recited as a "detection module" cannot perform the detection function.

Applicants submit that all elements required to perform detection need not be specifically recited in claim 36; as noted by the Examiner, these elements may vary depending on the detection technique

utilized. Again, the Examiner is respectfully reminded that the standard for 112 enablement is that one skilled in the art would be able to use the description of the invention to make and use the claimed invention. "An inventor need not, however, explain every detail since he is speaking to those skilled in the art". DeGeorge v. Bernier, 226 USPQ 758, 762 (Fed. Cir. 1985)

The Examiner further suggests that a counter electrode is required, and that fluid must exist in the device.

Applicants submit that the application of a potential between a conjugated detection electrode and a reference electrode is discussed at least on page 102, lines 14-19, page 106, lines 16-25, page 106 lines 31-32, and page 110, lines 4-9. The applicants respectfully remind the Examiner that "a patent need not teach, and preferably omits, what is well known in the art". Spectra-Physics, Inc. v. Coherent, Inc., 2 USPQ 2d 1737 (Fed. Cir. 1987). Furthermore, the standard for 112 enablement is that one skilled in the art would be able to use the description of the invention to make and use the claimed invention. "An inventor need not, however, explain every detail since he is speaking to those skilled in the art". DeGeorge v. Bernier, 226 USPQ 758, 762 (Fed. Cir. 1985). In this case, one of skill in the art would appreciate the presence of both counter-electrodes and fluids during operation of embodiments of the invention, given the teachings in the specification and the state of the art. Applicants respectfully remind the Examiner of the discussions on these points.

Applicants have amended claim 50 to recite "a device according to claim 49".

Applicants have amended claim 52 to recite a valve "in said second microchannel".

Accordingly, Applicants respectfully submit that the 35 U.S.C. §112, second paragraph, rejections of claims 36-39, 35-37, 49, 50, and 52-53 are improper, and should be withdrawn.

Claim Rejections – 35 U.S.C. §102

As a preliminary matter, Applicants note that the changes made by the American Inventors Protection Act of 1999 (AIPA) to 35 U.S.C. §102(e) do apply to the present application, despite its filing date prior to November 29, 2000 due to the further amendment to 35 U.S.C. §102(e) by the Intellectual Property and High Technology Technical Amendments Act of 2002 (H.R. 2215). Accordingly, Applicants respectfully request that the application be examined under 35 U.S.C. §102(e) as amended by the AIPA.

Claim 36 was rejected under 35 U.S.C. §102(e) as being anticipated by Segal et. al. (U.S. Patent Number 6,300,141).

The Examiner relies on Segal to demonstrate a support substrate, including a sample introduction region, a biosensor, a sample flow pathway in communication with said sample-introduction region and said biosensor. (Segal, col. 8, lines 47-53). Segal further discloses filters (col. 11, lines 36-53).

The Segal reference has a filing date of March 2, 2000, and claims priority to Provisional Application No. 60/122,546, filed March 2, 1999. Applicants submit that conception of the invention occurred prior to March 2, 1999 and was coupled with due diligence extending from prior to March 2,

1999 through the April 21, 1999 filing date of the present application. A declaration by the inventor, Jon F. Kayyem, submitted under 37 C.F.R. §1.131, referencing notes from a meeting dated prior to March 2, 1999, and several publications dated prior to March 2, 1999, is submitted herewith. Notes from a meeting prior to March 2, 1999 is attached as Exhibit 1. The notes indicate that microfluidics were discussed, and further that the combination of microfluidics and CMS technology was contemplated. In particular, separation and sample preparation were discussed.

As discussed in the interview, the main issue is the identification and description of what "CMS technology" was at the time, such that conception of the invention could be shown.

As outlined in the enclosed declaration by Jon Kayyem, at the time the notes were made, 'CMS technology' refers to electronic detection methods such as those outlined in Exhibits 2-6. As stated in the declaration, 'CMS technology' on or before March 2, 1999, included a detection well with a detection electrode having a self-assembled monolayer and a capture binding ligand. Further, as stated in the declaration, CMS technology included biochips having an inlet port, a detection well, and a channel between the inlet port and the detection well. It does not appear that the definition of "microfluidics" is at issue, due to the large usage of the term for many years. However, just for completeness, Applicants submit that microfluidic technology was widely publicly available prior to March 2, 1999 and included a solid support member, sample handling well, sample inlet port, and microchannels, as evidenced at least by Wilding et. al., U.S. Patent Number 5,304,487, issued April 19, 1994.

Accordingly, based at least on the enclosed declaration by Jon Kayyem and attached exhibits, Applicants respectfully submit that conception of the invention occurred prior to March 2, 1999 and that Applicants were diligent in constructively reducing the invention to practice from prior to March 2, 1999 through the April 21, 1999 filing date of the present application. In particular, based on the enclosed declaration, Applicants submit that at least the following elements have been demonstrated to be conceived prior to March 2, 1999: a sample preparation well and/or a separation well provided in a device including a detection well having a detection electrode including a self-assembled monolayer and a capture probe, where an inlet port coupled to a channel is provided for introducing fluid into the device.

Claim 36 recites a microfluidic device comprising a sample handling module, a first microfluidic channel extending between the sample handling module and an inlet port, and a second microfluidic channel extending between the sample handling module and a detection well.

The Examiner's attention is drawn to M.P.E.P. §715.03 'General Rule as to Generic Claims' stating "A reference or activity applied against generic claims may (in most cases) be antedated as to such claims by an affidavit or declaration under 37 C.F.R. §1.131 showing completion of the invention of only a single species, within the genus, prior to the effective date of the reference or activity." See *Ex parte Biesecker*, 144 USPQ 129 (Bd. App. 1964). See also *In re Fong*, 288 F.2d 932, 129 USPQ 264 (CCPA 1961); *In re Defaco*, 392 F.2d 280, 157 USPQ 192 (CCPA 1968).

Applicants respectfully submit that a sample separation well, conceived prior to March 2, 1999 as outlined in the enclosed declaration by Kayyem, were species within a genus of sample handling wells or

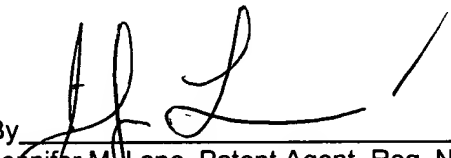
modules. In the specification on page 11, lines 4-5, it is disclosed that a separation module is one type of handling module. Accordingly, Applicants submit that the 37 C.F.R. §1.131 evidence showing completion of the invention with respect to a separation module or well is sufficient to show completion of the invention with respect to a sample handling well.

Accordingly, as supported by the enclosed 37 C.F.R. §1.131 declaration by sole inventor Jon F. Kayyem, Applicants submit that conception of the invention as claimed in claim 36 occurred in this country prior to March 2, 1999 and was followed by a diligent constructive reduction to practice commencing prior to March 2, 1999 and continuing through the April 21, 1999 filing date of the present application. Accordingly, the Segal reference does not have an effective date prior to the invention by Applicant's, and Applicant's respectfully request that the 35 U.S.C. §102(e) rejection of claim 36 be withdrawn.

CONCLUSION

Applicants submit the claims are in condition for allowance, and notification of such is respectfully requested. If after review, the Examiner feels there are further unresolved issues, the Examiner is invited to call the undersigned at (415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

By 
Jennifer M. Lane, Patent Agent, Reg. No. 51,916
for Robin M. Silva, Reg. No. 38, 304
Attorney for Applicants

Four Embarcadero Center - Suite 3400
San Francisco, California 94111-4187
Tel.: (415) 781-1989
Fax: (415) 398-3249
SF-1108749